UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VERAX BIOMEDICAL INC.,

Plaintiff,

v.

AMERICAN NATIONAL RED CROSS,

Defendant.

Civil Action No.: 1:23-cv-10335-PBS

AMERICAN NATIONAL RED CROSS'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

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INTRODUCTION

Plaintiff, Verax Biomedical Inc. ("Verax"), has a commercial challenge—it is flailing in its efforts to sell its PGD*prime* rapid test to hospital customers today. But rather than innovating or proving the value proposition of PGD*prime* to its hospital customers, Verax brings this case against the American National Red Cross ("Red Cross"), which is not Verax's competitor or supplier. As the pleadings show, the Red Cross has chosen to incorporate an innovative new technology, pathogen reduction, into its manufacturing processes to maximize the availability of blood platelets and make them safer for patients, as it must to comply with new U.S. Food and Drug Administration ("FDA") requirements. While Verax may not agree with this decision, the Red Cross's adoption of pathogen reduction technology did not violate any antitrust or other law and this case should be dismissed.

Verax's case turns on a fundamentally implausible premise. Verax alleges that the Red Cross—one of the nation's flagship non-profit humanitarian organizations—engaged in anticompetitive conduct to raise the price of platelets that the Red Cross collects from volunteer donors and sells to hospitals, and to foreclose Verax from selling its PGD*prime* product to hospitals in the after-market. Nothing about that theory makes sense.

The Red Cross is an instrumentality of the federal government tasked, among other things, with a responsibility to prevent and alleviate human suffering. 36 U.S.C. §§ 300101–300102. This includes ensuring the availability of the "critical life-saving product," blood platelets. *See* Compl. ¶ 3. The Red Cross does not operate for profit (Compl. ¶ 28) and is not motivated in any manner by a desire for gain. *See* 36 U.S.C. § 300102. These core principles drive all of its decision-making, including its decisions about how to implement the FDA requirement to manufacture

platelets in a way that mitigates potential bacterial contamination before distributing those platelets to hospitals for transfusion to patients. 21 C.F.R. § 606.145(a); *see* Compl. ¶¶ 47–55.

The FDA instituted the most recent version of this requirement in 2016 following years of growing awareness that platelets contaminated with bacteria could result in sepsis-related deaths. *See* 80 Fed. Reg. 29842, 29850 (May 22, 2015). When it adopted the regulation, the FDA made clear that it would issue evolving guidance on the precise methods that it approved to mitigate bacterial risk as it continued to evaluate and approve new methods. *Id.* The final FDA guidance—which was issued in December 2020 and sought compliance by October 1, 2021—approves only three manufacturing methods for mitigating bacterial risk in platelets: pathogen reduction technology ("PRT"), large volume delayed sampling ("LVDS"), and a primary culture followed by a secondary culture or rapid test.[1] Compl. ¶¶ 53–56. While the FDA was finalizing its guidance, the Red Cross began using PRT on some platelets and spent subsequent years studying the pros and cons of each approved bacteria mitigation method before determining that manufacturing most or all of its platelets using PRT was the best way for it to maximize platelet safety and availability, meet hospital demand and serve patients in need of transfusions. Compl. ¶¶ 48–55, 60, 63, 93, 97.

It is not a mystery why the Red Cross made this choice. As the complaint itself describes, PRT—which is manufactured and sold by Cerus Corporation ("Cerus") in the form of its INTERCEPT Blood System—is fundamentally different from other bacteria mitigation solutions made and sold by companies like bioMérieux SA ("bioMérieux") (which makes the testing system for both LVDS and primary/secondary culturing) and Verax. *See* Compl. ¶¶ 60–61, 63–92.

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[1] *See* FDA GUIDANCE FOR INDUSTRY, BACTERIAL RISK CONTROL STRATEGIES FOR BLOOD COLLECTION ESTABLISHMENTS AND TRANSFUSION SERVICES TO ENHANCE THE SAFETY AND AVAILABILITY OF PLATELETS FOR TRANSFUSION, (Dec. 2020), https://www.fda.gov/media/123448/download ("FDA December 2020 Guidance"); *see also* Compl. ¶ 54.

LVDS, primary cultures and Verax's PGD*prime* all involve sampling and testing platelet units. *Id*. ¶¶ 72–77, 82–87. Although they allow blood centers and hospitals to detect when a platelet dose is contaminated with bacteria, they (1) do not detect any other pathogens, and (2) do not inactivate pathogens of any kind (bacterial or otherwise). Further, when a platelet dose has a positive test result, the dose must be discarded, even if it is later determined the result was a false positive. All these tests do is detect which doses need to be thrown away. *Id.* PRT, by contrast, *inactivates* bacteria as well as viruses and other pathogens in platelets, as Verax acknowledges. *Id.* ¶ 63. This means that previously-contaminated platelets treated with PRT can still be safely transfused to patients—thereby saving doses that would otherwise have been discarded. *Id.* By buying and using PRT, the Red Cross has the ability to maximize the amount of FDA-compliant platelets available to the thousands of patients who need transfusions every day, all while better protecting those patients against a range of pathogens beyond just bacteria. *Id.* The Red Cross's decision to expand its use of PRT (while retaining LVDS as a second option during a transition period) was a sound choice for an organization that prioritizes health, safety and availability.

Verax—a private, for-profit corporation—is unhappy with the Red Cross's decision to use PRT, because it believes that hospitals that receive pathogen reduced platelets are less likely to use Verax's PGD*prime* in the after-market. But setting aside whether that is true or not (and why), the Red Cross's decision does not amount to an antitrust violation, an unfair business practice, defamation or tortious interference. Indeed, to accept Verax's position in this case would allow a private, for-profit business to force a non-profit humanitarian relief organization to forgo the FDA-approved path that it deems most responsive to hospital needs and best for patient safety given the nature of its operations. None of the laws at issue in this case support that outcome.

All of Verax's claims fail out of the gate for several independent reasons. *First,* Verax cannot maintain any antitrust claim under the Sherman Act because (1) the Red Cross is an instrumentality of the United States and therefore not a "person" who can be liable under that statute; (2) Verax does not and cannot allege that it buys from, sells to or competes with the Red Cross in the alleged market for "bacteria mitigation services" and thus it has not alleged that it suffered an "antitrust injury;" (3) the Red Cross cannot be liable for tying, monopolizing or attempting to monopolize "bacteria mitigation services," as Verax claims, when the Red Cross does not even sell that product and (4) Verax failed to allege that the Red Cross's use of PRT has harmed *competition* in a market for "bacteria mitigation services" as required to state a claim for exclusive dealing or attempted monopoly. All of these are independent grounds for dismissal of Verax's antitrust claims based purely on the allegations in the complaint and public record.

Second, Verax has failed to state any claim for relief under Massachusetts law because (1) none of the Red Cross's alleged statements are defamatory of Verax as a matter of law; (2) Verax has not alleged that the Red Cross's conduct interfered with any actual contractual relationship or customer and (3) Verax's Chapter 93A claim is derivative of other claims (that also fail) and, according to Verax's own allegations, the relevant events did not occur "primarily and substantially" in Massachusetts. The Court thus should dismiss the complaint in full.

BACKGROUND

A. As An Instrumentality Of The Federal Government, The Red Cross Serves A Unique And Critically Important Role For This Country

The Red Cross occupies a unique space in American history and has played a vital humanitarian role within society and the federal government for almost 150 years. Since its creation in 1881, the Red Cross has marshalled its network of donors, volunteers and partners to respond to emergencies; provide support to the U.S. Armed Services and military families; fulfill

the United States' international treaty obligations under the Geneva Convention and supply an array of life-saving services to individuals afflicted by disasters—all while prioritizing the needs of those in the most urgent cases of distress. 36 U.S.C. §§ 300101-300112. In recognition of its value to the United States, the Red Cross first received a Congressional charter in 1900, which Congress thereafter amended in 2007 to formally designate the Red Cross a "[f]ederally chartered instrumentality of the United States" with all of the rights accorded to that status. *Id*.

B. The Red Cross Is Committed To Platelet Safety and Availability

The Red Cross's blood services program is a core part of its mission to save lives and prevent and alleviate human suffering. Formed during World War II to address the military's urgent need for blood donations, the Red Cross pioneered the country's early blood banking system, and since then the organization has helped sustain the nation's civilian blood supply through its network of blood centers and volunteer (unpaid) donors.

Blood platelets are one of the products that the Red Cross collects, manufactures and sells to hospitals. Compl. ¶¶ 29, 34. Platelets are the cell fragments in blood that facilitate clotting and help stop bleeding. *Id*. ¶ 30. For that reason, platelets are frequently transfused to patients suffering from traumatic injuries, major surgeries, cancers and chronic diseases. *Id*. ¶¶ 31–32. Platelets, however, are susceptible to bacterial contamination which can cause sepsis and other health issues, and they have a short shelf-life before they can no longer be safely used. *Id*. ¶¶ 4, 46, 160. Accordingly, in May 2016, the FDA mandated that blood centers take FDA-approved measures to mitigate the risk of bacterial contamination. 21 C.F.R. § 606.145(a); Compl. ¶¶ 4, 47.

C. FDA Regulations Require The Red Cross To Mitigate The Risk Of Bacterial Contamination In Its Platelets Sold To Customers—This Is Not "Optional"

The FDA has made it clear that the Red Cross's obligation to mitigate the risk of bacterial contamination during the platelet manufacturing process is not optional. **It is against federal law**

for the Red Cross to sell platelets today without first taking measures to mitigate the risk of bacterial contamination. Specifically, FDA regulations not only require that "[b]lood collection establishments" like the Red Cross "assure that the risk of bacterial contamination … is adequately controlled;" they also mandate that blood centers do so using "FDA approved or cleared devices" or "other adequate and appropriate methods found acceptable for this purpose by FDA." 21 C.F.R. § 606.145(a). To date, the FDA has found only three methods "acceptable for this purpose:" (1) PRT, (2) LVDS and (3) a primary culture by the "blood collection establishment" followed later by a secondary culture or secondary rapid testing, typically performed by the hospital. *See* FDA December 2020 Guidance at 2–3; Compl. ¶¶ 53–56. Moreover, the FDA has "approved or cleared" only a limited number of "devices" that the Red Cross may use during its platelet manufacturing process. FDA December 2020 Guidance at 3. In short: The Red Cross cannot sell platelets unless they are FDA-compliant, and to be FDA-compliant, the Red Cross must manufacture its platelets using one of three bacterial mitigation methods approved by the FDA. *See* Compl. ¶¶ 47, 53–56.

D. Unlike Verax, The Red Cross Does Not Sell And Has Never Sold "Bacteria Mitigation Services" As The Complaint Uses That Term

Although the complaint is not a model of clarity, it appears to define "bacteria mitigation services" as the technology, equipment, or devices that the FDA has approved for hospitals or blood centers to use to mitigate the risk of bacterial contamination. Compl. ¶¶ 4, 56–58, 202. "Bacteria mitigation services" do not (apparently) encompass the various steps in blood centers' *manufacturing processes* to mitigate bacterial risk. This must be so because Verax alleges that its PGD*prime* test, bioMérieux's BacT/ALERT system and Cerus's INTERCEPT Blood System are all "bacteria mitigation services," *id.*; however, none of those companies perform bacterial mitigation on platelets. Instead, they manufacture equipment and tests that other entities (blood centers or hospitals) use to mitigate bacterial risk and, for INTERCEPT, address other pathogen

threats as well. *Id*. ¶¶ 86-87 ("Verax sells the FDA-cleared PGD*prime*, which is used [by hospital transfusion service staff] to *perform* a Rapid Test") (emphasis added); *id.* ¶ 76 ("bioMérieux SA manufactur[es] the BacT/ALERT microbial identification system, which can be used to *perform* LVDS") (emphasis added); *id.* ¶¶ 64–65 (Cerus "manufactur[es] the INTERCEPT Blood System," which is "performed on platelets shortly after they are collected").

Although the Red Cross sells FDA-compliant platelets, it does not sell "bacteria mitigation services." Instead, the Red Cross *buys* FDA-approved tests and technology (what Verax would call "bacteria mitigation services") from third parties—such as Cerus (for PRT) and bioMérieux (for the tests and tubes used in LVDS and previously, primary culturing)—and thereafter uses them to manufacture FDA-compliant platelets, as federal law requires. *Id*. ¶¶ 114, 278; *see id.* ¶¶ 64, 76. The FDA itself considers the Red Cross's purchase and use of bacteria mitigation technology (such as the INTERCEPT Blood System from Cerus) to be part of the Red Cross's "manufacturing process" of FDA-compliant platelets.[2]

E. The Red Cross Currently Buys Bacteria Mitigation Technology From Both Cerus (For PRT) And bioMérieux (For Tests Used In LVDS)

To meet the FDA's mandate and October 2021 deadline, and given PRT's unique ability to "treat" collected platelets by inactivating bacteria and other pathogens, the Red Cross began to buy Cerus's INTERCEPT Blood System technology to perform PRT (in addition to the bacteria mitigation technology the Red Cross was already buying from bioMérieux) and expanded its use of PRT over a period of years to improve platelet safety. *Cf.* Compl. ¶¶ 46–55 63–64, 72, 75–76, 84, 93, 97, 103. To date, Cerus's INTERCEPT Blood System remains the only FDA-approved

[2] *See*, *e.g.*, FDA GUIDANCE FOR INDUSTRY, MANUFACTURE OF BLOOD COMPONENTS USING A PATHOGEN REDUCTION DEVICE IN BLOOD ESTABLISHMENTS: QUESTIONS AND ANSWERS (Nov. 2021), https://www.fda.gov/media/153786/download.

version of PRT on the market. *Id*. ¶ 64. Although the Red Cross desires to manufacture all or almost all of its FDA-compliant platelets with PRT, the Red Cross continues to use bioMerieux's products to perform LVDS on a small portion of its platelets today. *Id*. ¶ 103.

F. Verax's After-Market *Test* Is A Completely Different Product From The Red Cross's *Platelets*; The Products Are Not Substitutes And The Parties Do Not Compete

Although Verax alleges that it makes and sells a "bacteria mitigation service" in the form of its PGD*prime* rapid test, unlike Cerus and bioMérieux, Verax does not sell that rapid test at the top of the supply chain to blood centers (like the Red Cross) who use bacteria mitigation technology to manufacture FDA-compliant platelets. Compl. ¶¶ 86–88. Nor does Verax do the same work as a blood center. Unlike the Red Cross, Verax does not manufacture FDA-compliant platelets or sell them to hospitals. Instead, Verax sells its PGD*prime* rapid test to hospitals as a way for the hospitals to use their own personnel (at their own expense) to detect bacteria and extend the shelf-life of *FDA-compliant platelets that hospitals have already purchased from blood centers*. Compl. ¶ 86-88 ("[PGD*prime*] is performed by hospital transfusion service staff . . . . on the day of the transfusion[.]"). This is a critical point: Because FDA regulations require blood centers to mitigate the risk of bacteria as part of their manufacturing processes, a hospital uses Verax's PGD*prime* rapid test on FDA-compliant platelets *after* a blood center has already met its obligations and performed some other form of bacterial mitigation during manufacturing. 21 C.F.R. § 606.145(a); Compl. ¶¶ 82–88. In short, Verax's test is not a substitute for any platelet product the Red Cross currently sells or has ever sold to hospitals.

ARGUMENT

I. VERAX'S SHERMAN ACT CLAIMS—COUNTS ONE, TWO AND THREE—FAIL FOR MULTIPLE INDEPENDENT REASONS

A. As A Federal Instrumentality, The Red Cross Is Not A "Person" Subject To The Sherman Act

Verax's Sherman Act claims against the Red Cross are legally deficient on virtually every level, as described at length throughout the rest of this motion. The Court, however, need not address any of those problems due to a threshold legal issue that is dispositive of all of Verax's antitrust claims. Because the Red Cross is a "[f]ederally chartered instrumentality of the United States" (36 U.S.C. §300101(a)), it is not a "person" who can be liable under the Sherman Act.

In Counts One through Three, Verax alleges that the Red Cross has violated Sections 1 and 2 of the Sherman Act. Compl. ¶¶ 270–71, 283, 303. However, both of those statutes impose liability only on a "person" who has engaged in the allegedly anticompetitive conduct. 15 U.S.C. §§ 1–2, 7. As the Supreme Court and its circuits have made clear, the federal government and its instrumentalities are not "persons" within the meaning of that law. *U.S. Postal Serv. v. Flamingo Indus. (USA) Ltd.*, 540 U.S. 736, 745–48 (2004) (explaining that the Sherman Act's definition of "person" does not include federal entities, like the Postal Service, because Congress did not intend to expose them to liability as an antitrust defendant (citing *United States v. Cooper Corp.*, 312 U.S. 600, 606–07, 609 (1941))); *Sea-Land Serv., Inc. v. Alaska R.R.*, 659 F.2d 243, 244 (D.C. Cir. 1981) ("Congress did not place the United States or its instrumentalities under the governance of the Sherman Act."); *see also, e.g.*, *IT & E Overseas v. RCA Glob. Commc'ns, Inc.*, 747 F. Supp. 6 (D.D.C. 1990) (holding federal instrumentality could not be liable for violations of the Sherman Act).

That, in particular, was the holding of the D.C. Circuit in *Sea-Land* and later, the Supreme Court in *Flamingo*. In *Sea-Land*, the D.C. Circuit rejected claims that the Alaska Railroad—a

federal instrumentality—violated the Sherman Act by conspiring with a competing private railroad to exclude competition. 659 F.2d at 244–47. After analyzing the legislative history, the Court of Appeals concluded that Congress did not intend for the federal government or its instrumentalities to be subject to liability under the statute, and thus they were not within the definition of "person" in the statute. *Id.* at 246 (rejecting plaintiff's attempt to use the "broad policy of the Sherman Act" as a reason to subject federal instrumentalities to liability under the antitrust laws). The court concluded that, notwithstanding plaintiff's complaints about fairness, Congress's actions meant that "a United States instrumentality [would] escape the regimen of antitrust laws [that] the Government would compel its rivals in commerce to obey." *Id.* at 247 (refusing to reach a contrary result absent explicit statutory language from Congress exposing the federal government and its instrumentalities to Sherman Act liability).

Following *Sea-Land*, the Supreme Court took up the question again in 2004, in *Flamingo*, where it reached the same result as the D.C. Circuit. In *Flamingo*, a manufacturer of mail sacks sued the U.S. Postal Service, alleging that the Postal Service was monopolizing mail sack production in violation of Section 2 of the Sherman Act, after the Postal Service terminated the plaintiff's contract to provide mail sacks. 540 U.S. at 738–39. After the district court granted the Postal Service's motion to dismiss, the Ninth Circuit reversed. *Id.* On appeal, the Supreme Court adopted the reasoning of the D.C. Circuit in *Sea-Land* and concluded that the Postal Service—an "independent establishment" of the government—could not be considered a "person" separate from the United States for purposes of Sherman Act liability. *Id*. at 744–47 (noting that *Sea-Land* set forth "the correct approach" and observing that, although the Postal Service was independent from the Government in several respects, it operated with "different goals, obligations, and powers from private corporations" and was defined by its "nationwide, public responsibilities"). Thus,

even though Congress waived the Postal Service's sovereign immunity from suit with a statutory "sue-and-be sued" clause, the Court held the Postal Service could not be subject to antitrust liability under the provisions of the Sherman Act. *Id.*

Three years after the Supreme Court decided *Flamingo* and made clear that federal instrumentalities do not fall within the definition of a "person" under the Sherman Act, Congress amended the Red Cross's congressional charter in 2007, codifying the Red Cross's status as an "instrumentality of the United States," 36 U.S.C. § 300101(a), with all of "the rights and obligations consistent with that status." *See* American National Red Cross Governance Modernization Act of 2007, H.R. 1681, 110th Cong. (2007). Although the Supreme Court had long recognized that the Red Cross operates "virtually as an arm of the Government" due to the vital role it plays for the federal government, *Dep't of Emp. v. United States*, 385 U.S. 355, 358–60 (1966), Congress's change to the Red Cross's statutory charter in 2007 put to rest any doubt about the Red Cross's instrumentality status (and its implications for this case). The Court should dismiss Counts One, Two and Three with prejudice because the Red Cross is not a "person" that can be sued under the Sherman Act.

B. Even If The Red Cross Were Subject To The Sherman Act, Verax's Antitrust Claims Would Fail For Independent Reasons

1. Verax Failed To Allege That It Suffered Antitrust Injury

The Court also should dismiss Counts One, Two and Three because Verax has not alleged any cognizable antitrust injury from the Red Cross's alleged anticompetitive conduct.

A separate, standalone element of every antitrust claim is that the plaintiff must allege not only that it personally suffered an actual injury (or impact) from the defendants' conduct, but also that its particular injury qualifies as an "antitrust injury." *Sterling Merch., Inc. v. Nestle, S.A.*, 656 F.3d 112, 121 (1st Cir. 2011). An *antitrust injury* is a very specific type; it must be "of the type

the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Id.* (*quoting Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977)).

As the First Circuit and numerous circuit courts have made clear, absent circumstances not applicable here, only consumers or competitors of the defendant in the allegedly restrained market are presumed to have suffered a cognizable antitrust injury. *See*, *e.g.*, *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 10 (1st Cir. 1999); *see also SAS of P.R., Inc. v. P.R. Tel. Co.*, 48 F.3d 39, 44–46 (1st Cir. 1995) (affirming that, to suffer an antitrust injury, the plaintiff must be a participant in the very market where competition is impaired and finding that the plaintiff who was neither a competitor nor consumer of defendant in the allegedly restrained market failed to show antitrust injury). Courts routinely find that parties that claim to have been "derivatively injured," such as suppliers to the defendant's allegedly injured customers, have not suffered antitrust injury. *SAS*, 48 F.3d at 45; *see also W. Penn Allegheny Health Sys. Inc. v. UPMC*, 627 F.3d 85, 102 (3d Cir. 2010) (typically only "consumers and competitors in the restrained market" suffer antitrust injury; a "supplier does not suffer an antitrust injury when competition is reduced in the downstream market in which it sells goods or services").[3]

The decision in *SAS* is particularly instructive. In that case, a supplier of pay phone technology sued the Puerto Rico Telephone Company, alleging the defendant violated Sections 1 and 2 of the Sherman Act by abandoning a planned project to upgrade its local pay phones, which would have utilized the plaintiff's technology. *SAS*, 48 F.3d 39. Affirming the district court's dismissal of the plaintiff's claims, the court concluded that the plaintiff failed to establish that it

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[3] *See also In re Aluminum Warehousing Antitrust Litig.,* 833 F.3d 151, 161–63 (2d Cir. 2016) (explaining that, to establish antitrust injury, it is not sufficient that a plaintiff participates in some market in which the defendant also participates, or participates in some market where the effects of anticompetitive conduct may be indirectly felt—unless the plaintiff is a customer, the parties must participate directly as competitors in the allegedly restrained market).

suffered antitrust injury, as the plaintiff failed to allege that it was either a customer (such as a property owner seeking a pay phone or a caller using long-distance service) or a competitor of the defendant (such as a rival provider of pay phones) in the allegedly restrained markets. *Id.* at 44–46 (finding that no other circumstances justified an exception to the general rule).

That analysis compels dismissal here too. For each of its antitrust claims, Verax contends that the allegedly restrained market is the market for "bacteria mitigation services," *i.e.*, the market for the technology and equipment used to mitigate bacterial risk. Compl. ¶¶ 96, 193–208. The Red Cross does not concede that "bacteria mitigation services" is a properly defined, relevant economic market. However, accepting it solely for purposes of this motion, the relevant legal question is whether Verax has alleged facts to show that it buys from or competes against the Red Cross in that *specific* alleged market. It has not.[4]

While Verax alleges that it sells a type of "bacteria mitigation service" to hospitals—that is, its PGD*prime* rapid test—the complaint itself makes clear that the Red Cross does not sell any such "services" as the complaint defines them. The complaint does not (and could never) allege that the Red Cross makes or sells any bacterial mitigation technology or equipment that blood centers or hospitals could use to manufacture FDA-compliant platelets initially or test them again later. Instead, the complaint specifically alleges that the Red Cross *buys* bacteria mitigation technology from third-party suppliers like Cerus and bioMérieux and uses it to manufacture FDA-compliant platelets.[5] Verax has not plausibly alleged that the Red Cross is a seller in the purported market for "bacteria mitigation services" at all, much less that the Red Cross directly competes

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[4] Verax does not allege that it has ever bought from or sold to the Red Cross itself.

[5] The fact that the Red Cross, as a non-profit organization that operates to provide humanitarian services while recovering its costs, informs its customers about certain new manufacturing costs, like PRT (*e.g.*, Compl. ¶ 199), does not transform the Red Cross into a "seller" of every input and technology it uses to manufacture its blood products.

with Verax in that market. Because the parties do not compete and Verax has not alleged any other cognizable theory of antitrust injury, the Court should dismiss Counts One, Two and Three.

2. Verax's Failure To Allege That The Red Cross Sells So-Called "Bacteria Mitigation Services" Dooms Its Tying And Monopoly Claims For Other Reasons

a. *The Law Does Not Allow Verax's Section 2 Claims Against An Organization That Does Not Sell The Allegedly Restrained Product*

In Counts Two and Three, Verax alleges that the Red Cross has violated Section 2 of the Sherman Act by monopolizing or attempting to monopolize the purported market for "bacteria mitigation services" through an array of allegedly anticompetitive acts. Compl. ¶¶ 276–305. These Section 2 claims fail for a basic reason: Verax failed to allege (and cannot allege) that the Red Cross is a seller in the purportedly restrained market. The offense of mono*poly* (as distinguished from the different offense of monop*sony*, which Verax has not and could not allege) is concerned only with the *sell* side of the market. *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., Inc.*, 549 U.S. 312, 320 (2007) ("[M]onopsony is to the buy side of the market what a monopoly is to the sell side"); *Todd v. Exxon Corp.*, 275 F.3d 191, 201–02 (2d Cir. 2001) (explaining the distinct legal standard the courts must apply in cases involving monopsony). Federal courts have not hesitated to reject Section 2 monopoly/exclusive dealing or attempted monopoly claims that—like here—fail to establish that the defendant actually competes in the allegedly constrained market as a seller of the relevant product. *See*, *e.g.*, *Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 603 F. Supp. 1077, 1087 (S.D. Ind. 1985), *aff'd,* 784 F.2d 1325 (7th Cir. 1986) (rejecting a Section 2 claim on the grounds that the defendant "cannot, as a matter of law, monopolize or attempt to monopolize the hospital services industry because [it] has never and does not now compete [as a seller] in that market."); *see also Name.Space, Inc. v. Internet Corp. for Assigned Names & Numbers*, 795 F.3d 1124, 1131 (9th Cir. 2015) (rejecting plaintiff's

monopolization claim because the defendant "[was] not a competitor in any of the three [alleged] markets" in the case and thus "[could not] serve as the basis for a § 2 monopoly claim.").

b. *Verax Cannot Sustain Its Section 1 Tying Claim When The Red Cross Does Not Sell The Tied Product At All*

This deficiency in Verax's complaint is also fatal to its Section 1 tying claim, because the Red Cross cannot possibly have engaged in the illegal tying arrangement that Verax alleges when the Red Cross does not even sell the purportedly "tied product:" that is, *technology or equipment* that a hospital or blood center can use to perform bacteria mitigation. Compl. ¶ 193–95. The type of tying claim Verax alleges requires allegations that the Red Cross used its power over the "tying product" to coerce a customer to purchase the second "tied product." *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984) ("[T]he essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product"), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). Thus, a threshold predicate for Verax's claim is allegations that the Red Cross has actually forced a sale of the "tied product." Verax failed to allege that.

As discussed above, Verax fails to allege (and could not allege) that the Red Cross sells the tied product **at all**. This is not a question of whether the Red Cross's FDA-compliant platelets themselves legally constitute one product or two. The relevant question is whether the complaint alleges facts that show the Red Cross actually sells the specific thing that the complaint has defined as the "tied product" in any form, bundled or otherwise. It does not. To the contrary, Verax expressly alleges that the only thing the Red Cross sells—FDA-compliant platelets "[t]reated" for bacterial mitigation—is the *tying* product, not the *tied* product. Compl. ¶¶ 186–88 (alleging that platelets "treated" with PRT constitute the *tying product*). Verax cannot maintain its tying claim in Count One when it failed to allege facts showing the Red Cross sells the allegedly tied product.

3. Verax Failed To Allege The Necessary Injury To Competition For Its Exclusive Dealing And Attempted Monopoly Claims

Finally, the Court also should dismiss Counts Two and Three for the independent reason that Verax has failed to allege facts to show that the Red Cross's use of PRT has injured *competition* in a purported market for "bacteria mitigation services" generally, as opposed to simply injuring Verax itself. Although Verax's claims for exclusive dealing in violation of Sections 1 and 2 of the Sherman Act, and attempted monopoly in violation of Section 2, are technically distinct antitrust claims, both require Verax to allege that the Red Cross's use of PRT harmed *competition*, *i.e.*, harmed the competitive process in the allegedly restrained market. *See, e.g.*, *Sterling*, 656 F.3d at 123–26 (exclusive dealing and Section 2 monopoly claims required plaintiff to show that the alleged conduct "impaired the competitiveness of the market").

Verax cannot make this required showing merely by alleging an injury to itself. *Id.* at 121–22. That is because "[t]he antitrust laws were enacted for 'the protection of *competition*, not *competitors*.'" *Atl. Richfield Co. v. USA Petroleum Co*., 495 U.S. 328, 338 (1990) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). As a result, Verax had to allege facts to show that the Red Cross's use of PRT harmed competition in the alleged market for "bacteria mitigation services" by, for example, reducing the nature or number of competitors in that purported market. *See E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n*, 357 F.3d 1, 8 & n.4 (1st Cir. 2004) (explaining that exclusive dealing contracts "pose a threat to competition only in very discrete circumstances" such as where courts have found that "they keep [a] competitor … from doing business in a relevant market") (citations omitted); *see id.* at 9 (affirming dismissal where plaintiff failed to adequately allege that contracts reduced the number of competitively available outlets in the market); *see also Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 65–66 (1st Cir. 2004) (exclusive dealing claim "requires a

showing of injury to competition . . . . [This] does not mean a simple loss of business [for the plaintiff] or even the demise of a competitor but *an impairment of the competitive structure of the market*") (emphasis added). Verax failed to do that.

Verax does not allege that the Red Cross's use of PRT reduced the number of competitors selling "bacteria mitigation services" or the nature of competition between them. In fact, Verax alleges almost nothing about competition in its purportedly relevant market at all. It does not allege (1) who competes with who in this market, (2) for what product(s) anyone supposedly competes, (3) for which customers anyone purportedly competes or (4) on what basis. Verax does not even identify the other competitors in this alleged market. Verax's failure to plead the necessary reduction in competition is particularly problematic here because, if anything, the complaint alleges an *increase* in the number of technologies and products available to mitigate bacterial risk. Whereas at one time the industry depended on primary culturing alone, with advancements in technologies and FDA approvals, secondary culturing/testing, PRT and LVDS have now become manufacturing options.[6] Compl. ¶¶ 48–55.

The complaint does contain allegations about the technologies that Cerus (PRT) and bioMérieux (LVDS) sell to blood centers like the Red Cross; however, Verax does not allege that it competes with either company (or anyone else) to sell its rapid tests to *blood centers*. Verax instead alleges that it sells its tests *to hospitals*. Compl. ¶ 86–88. And Verax never alleges that it competes with Cerus's INTERCEPT or bioMérieux's BacT/ALERT for sales to hospitals either. Compl. ¶¶ 97, 103 (alleging that blood centers, not hospitals, buy LVDS and PRT).

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[6] Because the technologies do different things and at different stages (*supra* at 2–3), Verax's allegations about cost differences between PRT, LVDS and its rapid test do not establish harm to competition. *E.g.,* Compl. ¶ 167.

The complaint's failure to allege facts about the nature of competition in a purportedly relevant market for "bacteria mitigation services" is not an innocent omission that amendment could readily cure. Verax's antitrust theories simply do not comport with the real world facts about how platelets are manufactured and sold in this country and the narrow role the PGD*prime* test plays in this ecosystem. At bottom the complaint merely alleges (for some reason Verax fails to articulate) that the Red Cross's use of PRT has resulted in Verax selling fewer of its rapid tests to hospitals than Verax would like. That is not sufficient to allege harm to competition as a matter of law.

II. VERAX FAILS TO STATE ANY CLAIM UNDER MASSACHUSETTS LAW IN COUNTS FOUR, FIVE AND SIX

A. Verax Fails To Allege That The Red Cross Published Statements That Were Defamatory Of Verax As A Matter of Law And Its Defamation Claim (Count Five) Fails

The Red Cross has never said anything remotely defamatory about Verax or its product, PGD*prime.* But even taking all of Verax's allegations as true, Count Five still fails. For a corporation to state a valid claim for defamation, the defendant's statements must "be reasonably susceptible of a defamatory meaning as to the corporation," which according to the Supreme Judicial Court is "a question of law." *Eyal v. Helen Broad. Corp.*, 583 N.E.2d 228, 232 (Mass. 1991) (citations omitted). Where statements refer only to a plaintiff's *product*—as opposed to the plaintiff itself—a plaintiff cannot establish defamation unless the statements suggest that "the plaintiff is dishonest or lacking in integrity, or that he is deliberately perpetrating a fraud upon the public by selling a product which he knows to be defective." *HipSaver, Inc. v. Kiel*, 984 N.E.2d 755, 762 n.6 (Mass. 2013) (noting authority that "[c]ourts generally are reluctant to impute a lack of integrity to a corporation merely from a criticism of its product") (citations and quotations omitted). *None* of the statements Verax cites are about Verax; only two even refer to Verax's

product PGD*prime*. Compl. ¶¶ 121, 124, 130. Since none of the Red Cross's alleged statements suggests that Verax lacks moral character, none can give rise to a claim for defamation.

B. Because Verax Does Not Allege The Red Cross Interfered With Any Contract, The Court Should Dismiss Its Tortious Interference Claim (Count Six)

Verax's tortious interference claim fares no better. To state a claim for tortious interference with a contractual relationship under Massachusetts law, Verax had to identify a specific contract that the Red Cross allegedly interfered with, or a specific Verax customer that the Red Cross "induced . . . to breach a contract or not to enter into or continue a business relationship" with Verax. *Vranos v. Skinner*, 930 N.E.2d 156, 165 (Mass. App. Ct. 2010) (quotations omitted). Verax has not done so. The complaint does not identify any actual hospital customer or specific contract that the Red Cross allegedly interfered with. Courts applying Massachusetts law frequently dismiss claims, like the one here, that rest on only conclusory generalized allegations of interference. *E.g. Sensitech Inc. v. LimeStone FZE*, 548 F. Supp. 3d 244, 258 (D. Mass. 2021) ("[A]llegations fall short of stating a plausible claim for tortious interference, . . . [where] they fail to identify any specific contract, relationship or opportunity that was lost.").[7] So too here.

C. Verax's 93A Claim (Count Four) Requires Dismissal On Multiple Grounds

Verax's 93A claim fails for two independent reasons. *First*, it is wholly derivative of the antitrust and tort claims, as the complaint concedes. *See* Compl. ¶ 309. Where a plaintiff fails to state a valid claim for relief as to the substantive claims underlying a derivative 93A claim, the derivative claim must also fail. *See* 52 Massachusetts Practice, Law of Chapter 93A § 4.3.[8]

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[7] *See also Curley v. Softspikes, LLC*, 2010 WL 2545611, at *3 (D. Mass. June 21, 2010) (dismissing tortious interference claim where "Plaintiffs make only the conclusory allegation that Defendants contracted directly with unidentified parties who otherwise would have contracted with [Plaintiffs]").

[8] *See*, *e.g.*, *Advanced Tech. Corp. v. Instron, Inc.*, 925 F. Supp. 2d 170, 183 (D. Mass. 2013) (dismissing Chapter 93A claim where underlying substantive claims failed).

Second, even if some or all of Verax's underlying antitrust and tort claims were to survive dismissal (though they should not), Count Four still fails because the complaint's own allegations cannot be squared with a finding that the Red Cross's alleged misconduct occurred "primarily and substantially within [Massachusetts]." MASS. GEN. LAWS ch. 93A, § 11. To determine where a defendant's alleged misconduct "primarily and substantially" occurred, courts focus on the "center of gravity of the circumstances that give rise to the claim." *Kuwaiti Danish Comput. Co. v. Digit. Equip. Corp.*, 781 N.E.2d 787, 798–99 (Mass. 2003). Here, Verax itself makes clear that there cannot be a "center of gravity" in Massachusetts for purposes of this case. To the contrary, Verax maintains that the relevant antitrust geographic market in this case is the United States, not Massachusetts. *See*, *e.g.*, Compl. ¶¶ 190, 203–204; *Fishman Transducers, Inc. v. Paul*, 684 F.3d 187, 197 (1st Cir. 2012) ("Where wrongdoing is not focused on Massachusetts but has [] substantial impact across the country, the 'primarily' requirement [] cannot be satisfied.").

Moreover, Verax never alleges facts showing that the Red Cross sent its allegedly defamatory statements "primarily and substantially" to hospitals in Massachusetts which then also acted upon those statements in the Commonwealth. *Sonoran Scanners, Inc. v. Perkinelmer, Inc.*, 585 F.3d 535, 546 (1st Cir. 2009) ("center of gravity" test predicated on deceptive statements focuses on where statements were "received and acted upon"). When a claim "fails to articulate [] where, if at all, [the relevant individuals] received or acted upon the misconduct, ... there is little indication that the unfair and deceptive practices took place primarily in Massachusetts." *Pine Polly v. Integrated Packaging Films IPF, Inc.*, 2014 WL 1203106, at *8 (D. Mass. Mar. 19, 2014) (emphasis added); *see* Compl. ¶¶ 122, 130. Verax's Chapter 93A claim thus fails.

CONCLUSION

For the reasons set forth above, the Court should dismiss the complaint in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent on April 17, 2023 to those identified as non-registered participants.

/s/ William J. Trach
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